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Re: Patent Term Extension
Application for
U.S. Patent No. Re. 34,879

An application for patent term extension under 35 U.S.C. § 156 for U.S. Patent No. Re. 34,879 was filed on May 8, 1995. U.S. Patent No. Re. 34,879 claims the medical device CPI® Ventak® P2 AICD™ System, which was subject to a regulatory review period within the meaning of 35 U.S.C. § 156 and was approved for commercial marketing or use on March 10, 1995.

U.S. Patent No. 4,998,531 ('531 patent), issued on March 12, 1991 from an application filed on March 28, 1990 and was reissued as U.S. Patent No. Re. 34,879 on March 14, 1995. Effective June 8, 1995, 35 U.S.C. § 154 was amended to provide for patents that were in force on June 8, 1995 to have a term which is the longer of 17-years from date of issue of the patent or 20 years from the filing date of the application that led to the patent. Since Reissue Patent No. 34,879 was in force on June 8, 1995, the patent is entitled to an expiration date which is the later of 17-years from the issue date of the '531 patent (March 12, 2008) or 20-years from the filing date of the application that led to the '531 patent (March 28, 2010). Accordingly, the expiration date of the reissue patent is March 28, 2010, twenty years from the filing date of the application that led to the '531 patent.

The length of the extension which may be granted for a patent eligible for extension cannot exceed fourteen years from the date of approval of the approved product. 35 U.S.C. § 156(c)(3). Under the circumstances of this application for patent term extension, the twenty-year term of the subject patent (due to expire March 28, 2010) will not expire until almost a year after the critical limit for an extension of fourteen years from the approval date (i.e. March 10, 2009). Even though the subject patent may meet all of the requirements of eligibility for patent term restoration under 35 U.S.C. § 156(a),¹ the application fails to provide a *prima facie* showing that the term of

¹It is noted that on June 7, 1995 a Federal Register Notice was published which stated that patents that were in force on June 8, 1995 would be entitled to the longer of the original seventeen year term plus any extension under 35 U.S.C. § 156 or a twenty-year term ("Final Determination," 60 Fed. Reg. 30069-71). This Notice was criticized in the decision of the Court of Appeals for the Federal Circuit in *Merck & Co. v. Kessler*, 38 USPQ2d 1347 as it decided that an extension under 35 U.S.C. § 156 could be added to a twenty-year term if the seventeen year term expired after June 8, 1995, provided that the fourteen-year limit of 35 U.S.C. § 156(c)(3) was not exceeded.

U.S. Patent No. Re. 34,879 could be extended under 35 U.S.C. § 156.

The application for patent term extension is dismissed as moot.



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RE: CPI® Ventak® P2 AICD™
FDA Docket No.: 95E-0183